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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/762,769      | 01/21/2004  | Anastasios Melis     | BERK-016CIP         | 3105             |

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                 |                              |  |
|------------------------------|---------------------------------|------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/762,769   | Applicant(s)<br>MELIS ET AL. |  |
|                              | Examiner<br>Ganapathirama Raghu | Art Unit<br>1652             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 6, 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/04 3/23/06</u> | 6) <input type="checkbox"/> Other: _____  |

***Application Status***

In response to the Office Action mailed on April 04, 2006, applicants', filed a response and amendment received on July 06, 2006. Said amendment, amended claims 1-3, 6 and 9 and canceled claims 4-5, 7 and 10-31. Thus, claims 1-3, 6, 8-9 are pending in the instant Office Action and are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

***Withdrawn- Claim Rejections 35 USC § 101***

Previous rejection of Claims 1-9 under 35 U.S.C. 101 is withdrawn in view of the applicants' amendment of claims 1-3, 6 and 8-9.

***Withdrawn- Claim Rejections 35 USC § 112***

Previous rejection of claims 1-9 under 35 U.S.C. 112 second paragraph is withdrawn in view of the applicants' amendment of claims 1-3, 6 and 8-9.

***Withdrawn- Claim Rejections 35 USC § 103***

Previous rejection of claims 1-9 under 35 U.S.C. 103 for obviousness is withdrawn in view of the applicants' amendment of claims 1-3, 6 and 8-9.

***New- Claim Rejections 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the phrase "...ablation...", it is not clear to the examiner what this phrase encompass? Clarification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of hydrogen gas generation by culturing genetically modified algae under suitable conditions, said modification involves the disruption of chloroplast sulfate permease (*CrcpSulP*) comprising SEQ ID NO: 2 and encoded by the polynucleotide sequence of SEQ ID NO: 1, modified by anti-sense technology to reduce the level of said *CrcpSulP* expression by at least 50% by specific anti-sense constructs namely; *asulp* 17, *asulp* 22 and *asulp* 29 (paragraph 00120 and Fig. 13 of Specification) as compared to unmodified wild-type algae, does not reasonably provide enablement for a method of hydrogen gas generation wherein said *CrcpSulP* comprising SEQ ID NO: 2 and encoded by the polynucleotide sequence of SEQ ID NO: 1 is being genetically altered by any anti-sense sequence to *CrcpSulP* or any method to reduce the level of said *CrcpSulP* expression by at least 50% as compared to unmodified wild-type algae. Even for the anti-sense constructs *asulp* 17, *asulp* 22 and *asulp* 29 the sequence structures are not provided. The specification does not enable

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any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not support the broad scope of the claims which encompass a method of hydrogen gas generation by culturing genetically modified algae under suitable conditions, said modification involves the disruption of chloroplast sulfate permease (*CrcpSulP*) comprising SEQ ID NO: 2 and encoded by the polynucleotide sequence of SEQ ID NO: 1 by any method because the specification does not establish: (A) all the methods to reduce *CrcpSulP* comprising SEQ ID NO: 2 and encoded by the polynucleotide sequence of SEQ ID NO: 1 activity in algae, for example, expression level of a gene of interest can be down regulated by i) affecting the regulatory regions of the gene namely promoter region, transcriptional initiation, translational initiation, poly A adenylation etc., ii) interfering with protein/protein interactions i.e., interaction of the gene of interest with other interacting partners, iii) it is also not clear to the examiner whether insertion of sense strand involves the entire strand which would result in overexpression or involves expression of certain specific critical domains of *CrcpSulP* that are involved in affecting the expression or the activity of full-length mature polypeptide *CrcpSulP*. Therefore, structural knowledge of *CrcpSulP* gene regulatory elements, structural knowledge of specific and critical domains of *CrcpSulP* polypeptide that could potentially interfere with the activity or the expression levels of said protein and the structural knowledge of any other interacting partners of *CrcpSulP* involved in modulating the activity and expression would be necessary to the other methods encompassed by the instant claims to bring about the desired effect, but is not provided by the specification or prior art; and (B) the specification provides

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insufficient guidance as to which of the essentially infinite possible choices are likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim

In view of the great breadth of the claims, amount of experimentation required to make the claimed method of hydrogen gas production in a genetically modified algae by any method, the lack of guidance, working examples, and unpredictability of the art in predicting the utility of the claimed invention, would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the method of hydrogen gas generation in a genetically modified bacteria by any method of disrupting *CrcpSulP* comprising SEQ ID NO: 2 and encoded by the polynucleotide sequence of SEQ ID NO: 1 encompassed by the claims. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods of gene disruption broadly encompassed by the claims.

### ***Summary of Pending Issues***

The following is a summary of issues pending in the instant application.

1) Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

2) Claim 9 is allowable if amended, as currently said claim 9 depends from a rejected claim 8.

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### *Conclusion*

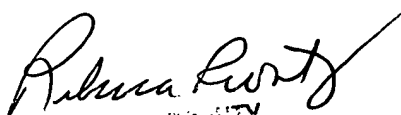
None of the claims are allowable. Claims 1-3, 6 and 8 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.  
Patent Examiner  
Art Unit 1652

Sept. 09, 2006.

  
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